Report to Congress

Implementation of Section 3507 of the
Patient Protection and Affordable Care Act of 2010

Third Progress Report

Food and Drug Administration

_____ Date _____

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Introduction and Background

In March 2010, President Obama signed into law a comprehensive health reform bill, the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (codified at note following 42 U.S.C. section 18001), and a package of amendments to the Affordable Care Act, the Health Care and Education Reconciliation Act of 2010 (HCERA; P.L. 111-152).

Subsection 3507(a)[1] of the Affordable Care Act requires the Secretary of Health and Human Services (the Secretary), acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in standardized format (similar to "Drug Facts" on over-the-counter products) to the promotional labeling or print advertising of such drugs would "improve health care decision-making by clinicians and patients and consumers."

Subsection 3507(b) of the Affordable Care Act requires the Food and Drug Administration (FDA) to consider research in the areas of social and cognitive psychology and to consult drug manufacturers, clinicians, patients and consumers − specifically "experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health."

Finally, subsection 3507(c) of the Affordable Care Act directs the Secretary to submit a report to Congress outlining its determination under subsection (a). If FDA determines that adding these types of standardized risk/benefit summary statements (or tables) to advertising or promotional labeling for prescription drugs would improve health care decision making, subsection 3507(d) of the Affordable Care Act directs the Agency to promulgate proposed regulations setting forth such requirements.

Currently available research does not provide a sufficient scientific basis to support the required determination. At the time of submission of the first progress report under the Affordable Care Act (March 2011), FDA estimated that the necessary studies, literature review, and consultation with appropriate experts would take roughly three years. These studies are well underway, and an updated timeline for the completion of this work is provided below. If, after these steps are completed, FDA determines that the addition of standardized summary statements would improve health care decision making, FDA will promulgate proposed regulations.

This is the third and final annual progress report to Congress detailing the progress that has been made toward fulfilling the requirements of the law. The Secretary will report its final determination to Congress in the fall of 2013.

Steps for Implementation of Section 3507

To implement the provisions of section 3507, FDA will:

- Determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or "Drug Facts" box) to the

[1] Pub. L. No. 111-148, section 3507, 124 Stat. 119, 530 (codified at note following 21 U.S.C. section 352).

promotional labeling or print advertising of such drugs would improve health care decision making by clinicians, patients and consumers. Because currently available research on the communication of quantitative information in prescription drug promotion is not sufficient to support the required determination, FDA is conducting three studies to address this task.

- ***Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs (Quantitative Study)***. The purpose of this study is to investigate the value of adding quantitative benefit and risk information to DTC advertisements for prescription drugs and to explore a variety of ways to present that information, including numerically and graphically.

  Results: Our findings demonstrate that participants can accurately recall quantitative benefit information from DTC prescription drug print and television ads for a mock prescription drug and that providing this information does not adversely influence their recall or perceptions of the product's risk. Overall, presenting information using absolute frequency and percent formats may be best to help participants accurately recall how well a drug works. Presenting a visual aid also appears to help participants accurately recall how well a drug works, with bar charts and tables demonstrating advantages over other visual formats. In general, providing information to participants enables them to see the information and answer questions about it correctly, although it does not necessarily change: (1) their attitude toward the drug, (2) their perception of how well the drug works and how risky it is, or (3) their intentions to get more information about the drug or to take the drug. At the same time, including quantitative benefit information did not have a detrimental effect on the recall of risk information (completed March 30, 2012).

- ***Study of Clinical Efficacy Information in Professional Labeling and DTC Print Advertisements for Prescription Drugs (Display Page Study).*** The purpose of this two-part study is to understand how physicians and consumers, respectively, make risk/benefit assessments from labeling and advertising. In particular, we will examine how consumers make such judgments in response to variations in the efficacy presentations in the "display" (first) page of a DTC print advertisement and how physicians make similar judgments from professional labeling. Data analysis and interpretation are ongoing.

- ***Study of Format Variations in the Brief Summary of DTC Print Advertisements (Format Study).*** The purpose of this study is to systematically examine the type of information that could be presented in a standardized box (i.e., the addition of quantitative and qualitative information in a box format) and the level of efficacy or risk to determine whether and how to add qualitative and quantitative benefit and risk information to the Brief Summary. Data analysis and interpretation are ongoing.

We believe that the results from these studies will inform FDA's determination about the usefulness of quantitative summaries of the benefits and risks of prescription drugs in both promotional labeling and print advertising.

- Review all available scientific evidence and research on decision making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health. To do this, FDA:

    - Contracted with a research firm to conduct a review of available scientific literature (completed February 17, 2012).

    - Presented the results of the literature review and this topic generally to the FDA Risk Communications Advisory Committee (RCAC), allowing us to consult with external experts in the field (meeting held November 17, 2011).

- Collaborated with two researchers who have contributed to the scientific literature on this issue to evaluate potential methods for, and the utility of, applying a "Drug Facts" box-format for summarizing risks and benefits of products with multiple indications and/or multiple clinical trials. We examined the presentation of clinical trial data in prescription drug labeling and discussed ways to improve their usefulness and comprehensibility. We found that the variable amount and nature of data available for different drugs makes developing a standard format a challenge (e.g., some drugs have many critical studies, multiple claims, boxed warnings, many precautions, complex dosing instructions (completed May 10, 2012).

- Submit to Congress a report that provides (1) the determination by the Secretary under section 3507(a) and (2) the reasoning and analysis underlying that determination.

If FDA determines that it would improve health care decision making by clinicians and patients and consumers, it will promulgate proposed regulations for implementing quantitative summaries of Drug Benefit & Risk Information. The content will be determined after completion of research, review of scientific evidence, and consultations with the RCAC and external experts.

Workplan for Implementation of Section 3507

Promulgate proposed regulations (if applicable)		Fall 2015
Completed Work		
First Progress Report to Congress		Completed March 23, 2011
Second Progress Report to Congress		Completed May 25, 2012
Literature Review		Completed February 17, 2012
FDA Risk Communications Advisory Committee (RCAC) Meeting		Completed November 17, 2011
Quantitative Study		Completed March 30, 2012
Ongoing Work		
Display Page Study	Status	Data analysis in progress
	Target Date of Completion	July 2013
Format Study	Status	Data analysis in progress
	Target Date of Completion	July 2013
Third Report to Congress		July 2013
Analysis and determination; preparation of final summary report		Spring 2012 – Fall 2013
Final Summary Report to Congress (This report will include the results of FDA's evaluation and determination under section 3507(a).)		Fall/Winter 2013

Conclusion

FDA aims to enhance the public health through improved health care decision making by clinicians, patients, and consumers. As reflected in this report, a variety of steps will provide the scientific basis for the appropriate implementation of the requirements of section 3507, including a thorough review of all applicable literature, consultation with outside experts in relevant fields, and empirical research. This third progress report updates our timeline for completing the work required to implement section 3507 of the Affordable Care Act and provides the current status of the work. FDA will issue a final report after completion of the analyses and interpretation of the studies and will then determine whether proposed regulations are appropriate.